REMARKS/ARGUMENTS

In response to the Final Rejection mailed February 2, 2005, Applicants have amended claim 1, added new claims 55 and 56 and present the following remarks. Claims 1-4, 6-23, 29, 37-40 and 54-56 are pending. Claims 5, 24-28, 30-36 and 41-53 have been canceled.

Support for claims 55 and 56 may be found in several places. Since the examples produce the polypeptide recombinantly in plants, plant extract compositions are supported. Furthermore, since the absence of adjuvants is emphasized in several locations (page 9, line 18, page 51, line 14, etc.) and original claims, that language is also supported.

Claims 1-10 and 19 were rejected under 35 USC 101 as being non-statutory subject matter. The examiner contends that the claimed polypeptide self-antigen is not different from the corresponding naturally occurring polypeptide. This rejection is respectfully traversed.

In addition to the features pointed out in the response filed November 17, 2004, it should be noted that the naturally occurring tumor protein in natural form apparently does not induce an immune response in the patient because the patient would be self-cured. The present claims recite the protein in a form that is recognized by the immune system. While not wishing to be bound by any theory, others have suggested that tumor antigens are not recognized by the immune system because they are bound to a cell that contains components that mask or otherwise prevent the immune system from recognizing the tumor antigen. The present claims recite that the polypeptide is "purified" and thus not in the naturally occurring form. Accordingly, the rejection should be withdrawn.

Claims 1-4, 6-23, 29, 37-40 and 54 were rejected under 35 USC 112, second paragraph as indefinite in several recitations.

Claim 1 was considered indefinite by reciting "encoded at least in part". The examiner contends that the part encoded is unclear. Claim 1 is clear, but to be redundant claim 1has been amended to recite that the "part" of the nucleic acid in the cells of said

tumor encodes a surface immunoglobulins epitope. Since B-cell lymphomas are generally clonal, this language is quite precise.

Claim 1 was considered indefinite by reciting, "at risk of developing a tumor, encoded at least in part by ...". Applicants submit the examiner is misreading the claim. A comma occurs after "tumor". The claim recites "a subject with a B-cell lymphoma tumor or at risk of developing the B-cell lymphoma tumor," The language "or at risk of developing the B-cell lymphoma tumor" refers to the subject, not a polypeptide or nucleic acid. The term "at risk of developing the B-cell lymphoma tumor" only superficially appears to refer to everyone. The term recites "the B-cell lymphoma tumor" meaning the one from the patient. Since B-cell lymphomas are generally clonal, the sentence would only make sense when the individual at risk is one currently or previously exposed to the particular B-cell lymphoma tumor. Accordingly, the rejection should be withdrawn.

Claim 23 was considered indefinite in the recitation "at least about". The examiner contends that it is unclear what range of activity is covered because of the broad language. This rejection is traversed. From earlier claim 20 from which claim 23 depends, the amount is sufficient to induce a polyclonal anti-idiotypic antibody response or a cell mediated immune response. This functional range is further redefined by an amount, which is required to produce the recited function. According, there is nothing indefinite in the use of this term in the present context.

Claims 1-4, 6-23, 29, 37-40 and 54 were rejected under 35 USC 112, first paragraph, for lack of enablement. The debate revolved around the word "vaccine" and the examiner asserting "there is no teaching in the prior or post filing are or in applicant's specification indicating that B-cell lymphomas can be prevent or cured..." The rejection is respectfully traversed and the examiner's statement is factually wrong.

While the word "vaccine" is open to misinterpretation, applicants have given the composition to patients who at the time were in remission with no sign of current disease. The specification examples demonstrate the use and usefulness of the vaccine in humans. The results of FDA phase I clinical trials have been published with the vast majority of patients displaying a tumor specific immune response in response to vaccination. Accordingly, this rejection should be withdrawn.

Claims 1-11, 17-23, 29 and 37-40 were rejected under 35 USC 112, first paragraph as enabling only B-cell lymphoma surface immunoglobulin antigens having the full complement of both VH and VL domains of 3 CDRs each. This rejection is respectfully traversed.

This assertion is speculation on the part of the examiner. While one may wish to have as much of the immunoglobulin idiotype as possible, it is not resolved that the full complement is needed. From applicant's specification, it has been shown that a single chain molecule alone is adequate even though it is an artificial molecule with considerably less than the naturally occurring two-chain tumor antigen. The actual minimal structure needed to fulfill the requirements of claimed feature (d), ...inducing an immune response... is not known.

The examiner has cited Benevenuti et al to suggest that the polypeptide should mimic the idiotype of the tumor antigen. A through discussion of Benevenuti et al is in the response filed November 17, 2004. This may be true but it does not indicate that the entire idiotype is needed or what portions of the idiotype are important. Furthermore, each patient's tumor antigen idiotype appears to be different (at least for the ones tested so far), thus it is even less clear that all 6 CDRs are required. Therefore, it is unreasonable to require what might be unnecessary. Accordingly, the rejection should be withdrawn.

Claims 1-4, 6-13, 17-22, 29, 38 and 54 were rejected under 35 USC 102(b) as being anticipated by Casper et al. The examiner contends that the fusion protein vaccine taught is the same as that claimed. This rejection is respectfully traversed.

The fusion protein of scFv-GM-CSF in Caspar et al is different from the claimed invention because the present invention is capable of inducing an immune response without an adjuvant. The Caspar et al fusion protein has the adjuvant GM-CSF present as an integral part of the molecule and therefore cannot meet the claim recitation.

The scFv (2A12) gene without the GM-CSF taught by Casper et al is in an adenovirus nucleic acid. Casper et al uses the nucleic acid containing virus without a scFv protein. A protein corresponding to scFv (2A12) as a protein is not taught by Casper et al and is not taught by Casper et al to be used to inoculate an animal. While the examiner assumes that the gene is expressed in vivo and thus simultaneously

inoculates the animal, which merely shows that an infected animal may generate an immune response. It is still a missing teaching to show production of the claimed polypeptide with the claimed features. Furthermore, the present claims have been amended to recite that the polypeptide is purified. Without even having the polypeptide outside an animal, purification of the polypeptide is not shown. Still further, new claim 54 requires that the purified protein not be conjugated or fused to another protein. An unfused or unconjugated polypeptide composition has not been shown. Even if the hypothesized compound could have been made, it still is not in purified form as claimed. Therefore, for this and the reasons given before, Casper et al does not disclose the polypeptide molecule as claimed.

Claims 1-4, 6-12, 17-23, 29, 38 and 54 were rejected under 35 USC 102(b) as being anticipated by Hawkins et al. The examiner contends that Hawkins teaches an scFv mimicing the surface immunoglobulins of a B-cell lymphoma used as a vaccine. This rejection is respectfully traversed.

As with the naked DNA immunization in Caspar et al, there is production of or vaccination with the polypeptide. The claims are directed to a purified polypeptide, not a DNA construct or a potential polypeptide made in vivo but never purified. Without a showing of a polypeptide with the claimed features, Hawkins et al does not anticipate the claims. The other comments provided before still apply. Accordingly, the rejection should be withdrawn.

Claims 1-4, 6-23, 29, 37-40 and 54 were rejected under 35 USC 103 as being unpatentable over Caspar et al in view of Fiedler et al, Tang et al and Hakim et al. Caspar et al was applied above. The basis for the rejection is presumed to be the same as previously. This rejection is respectfully traversed.

The final rejection mailed February 2, 2005 partially repeats applicant's arguments and mischaracterizes others. Rather than rebutting these arguments, the examiner's position is a simple conclusion without support for the claimed features not taught or suggested by any of the applied references. Therefore, the rejection still does not suggest the present invention and therefore the rejection should be withdrawn.

The amendment to the specification is objected to under 35 USC 132 as introducing new matter into the specification. The specification has been amended as suggested by the examiner.

Claims 1-4, 6-23, 29, 37-40 and 54 were rejected under 35 USC 112, second paragraph, as being indefinite as "totally unclear what peptide is encoded by said nucleic acid." Note the presence of a comma in Claim 1 reciting "A purified polypeptide... , encoded at least in part by a nucleic acid ... It should be clear to all that the nucleic acid at least partially encodes the claimed polypeptide of the claim 1. The examiner has asked if the nucleic acid encodes a peptide with only some sequence overlap to the claimed polypeptide. The answer is yes. From the specification, it is apparent that applicants' preferred embodiment is a single chain antibody, which use part of the sequences from two different genes, VH and VL and synthetic linker sequences.

Claim 1 is said to lack antecedent basis for "said nucleic acid". The only appearance of "said nucleic acid" in claim 1 is in step (b) reciting, "... by said nucleic acid in the cells of said tumor..." The term has antecedent basis in the preamble, which recites "...by a nucleic acid in the cells of said tumor..." The same context for the term is distinguishes this nucleic acid from any other nucleic acid and thus antecedent basis is present.

Claim 54 is rejected under 35 USC 112, first paragraph as failing to have a written description in the specification. The alleged NEW MATTER is the claim stating that the polypeptide is not fused or conjugated to another polypeptide.

Support for the language "not fused or conjugated to another polypeptide" is found explicated and implicated in many places. At the top of page 5, mention is made of idiotype vaccines that are conjugated. The first sentence of the next paragraph indicated that that method is not acceptable. Page 21, lines 4-6 states, "These products are defined as being "inherently immunogenic" so that potent immune responses to them are generated without the need to resort to conjugation to carrier molecules..." Thus support for not being conjugated to another polypeptide is present.

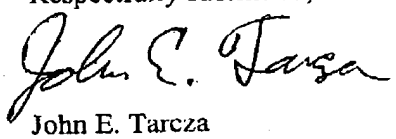
Support for the language "not fused" may be seen on page 51, the section for Formulation of the Polypeptide Vaccine. Line 11-14 states that the protein/peptide is "...so effective immune responses are generated in the absence of exogenous (or fusion protein)..." Thus support for compositions not being fused to another polypeptide is present.

Claims 1-4, 6-23, 29, 37-40 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over co-pending application 10/067,790 in view of Hawkins et al. Applicants request such an issue be resolved (most likely by terminal disclaimed) once the claims are in condition for allowance in either 10/067,790 or the present application.

In view of the above amendments and comments, the claims are now in condition for allowance and applicants request a timely Notice of Allowance be issued in this application. If needed, applicants petition for sufficient extension of time for consideration of this paper.

The commissioner hereby is authorized to charge payment of any fees, including extension of time fees, under 37 CFR § 1.17, which may become due in connection with the instant application or credit any overpayment to Deposit Account No.500933.

Respectfully submitted,



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Attachments: Petition for a Three-Month Extension of Time

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